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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/779,890	02/17/2004	Stéphcn Shaughnessy	MDSP-P04-180	1480

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EXAMINER

KEMMERER, ELIZABETH

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 09/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/779,890

Applicant(s)

SHAUGHNESSY ET AL.

Examiner

Elizabeth C. Kemmerer, Ph.D.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 and 34-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-28,34-49 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3, 28 and 49 (each in part), and 4-9, drawn to a process of increasing bone density comprising inhibiting the formation of a tertiary complex of IL-11, IL-11R and gp130 by administering a mutant IL-11R, classified in class 514, subclass 2, for example.
- II. Claims 1-3, 28 and 49 (each in part), and 10, drawn to a process of increasing bone density comprising inhibiting the formation of a tertiary complex of IL-11, IL-11R and gp130 by administering an anti IL-11 antibody, classified in class 424, subclass 130.1, for example.
- III. Claims 1-3, 28 and 49 (each in part), 11-13, 40, drawn to a process of increasing bone density comprising inhibiting the formation of a tertiary complex of IL-11, IL-11R and gp130 by administering an IL-11 binding peptide, classified in class 514, subclass 12, for example.
- IV. Claims 1-3, 28 and 49 (each in part) and 14, drawn to a process of increasing bone density comprising inhibiting the formation of a tertiary complex of IL-11, IL-11R and gp130 by administering a small molecule, classified in class 514, subclass 1, for example.
- V. Claims 1-3, 28 and 49 (each in part) and 15, drawn to a process of increasing bone density comprising inhibiting the formation of a tertiary

complex of IL-11, IL-11R and gp130 by administering an IL-11 antagonist, classified in classification dependent upon structure of antagonist.

- VI. Claims 1-3, 28 and 49 (each in part) and 16, drawn to a process of increasing bone density comprising inhibiting the formation of a tertiary complex of IL-11, IL-11R and gp130 by administering an IL-11R binding peptide, classified in class 514, subclass 25, for example.
- VII. Claims 1-3, 28 and 49 (each in part), 17 and 45, drawn to a process of increasing bone density comprising inhibiting the formation of a tertiary complex of IL-11, IL-11R and gp130 by administering an IL-11R antibody which inhibits interactions between IL-11 and IL-11R, classified in class 424, subclass 130.1.
- VIII. Claims 1-3, 28 and 49 (each in part), 18 and 46, drawn to a process of increasing bone density comprising inhibiting the formation of a tertiary complex of IL-11, IL-11R and gp130 by administering an IL-11R antibody which inhibits interaction between IL-11R and gp130, classified in class 424, subclass 130.1.
- IX. Claims 1-3, 28 and 49 (each in part), 19-27, drawn to a process of increasing bone density comprising inhibiting the formation of a tertiary complex of IL-11, IL-11R and gp130 by administering a transcribable genetic material, classified in class 514, subclass 44, for example.
- X. Claims 34-39 and 43, drawn to compositions comprising an IL-11 binding peptide, classified in class 530, subclass 350, for example.

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- XI. Claims 41 and 42, drawn to method of using an IL-11 binding peptide to purify IL-11, classified in class 514, subclass 412, for example.
- XII. Claim 44, drawn to composition comprising IL-11R binding peptide, classified in class 530, subclass 300, for example.
- XIII. Claims 47 and 48, drawn to use of assays to identify IL-11 antagonists, classified in class 436, subclass 501, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions X and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the compositions of Invention X can be used to purify IL-11.

Inventions XII and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the compositions of Invention XIII can be used to purify IL-11R.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to

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constitute patentably distinct inventions for the following reasons: Groups I-IX, XI, and XIII are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention I requires administration of a mutant IL-11R protein, which is not required by any of the other groups. Invention II requires administration of an anti IL-11 antibody, which is not required by any of the other groups. Invention III requires administration of an IL-11 binding protein, which is not required by any of the other groups. Invention IV requires administration of a small molecule, which is not required by any of the other groups. Invention V requires administration of an IL-11 antagonist, which is not required by any of the other groups. Invention VI requires administration of an IL-11R binding peptide, which is not required by any of the other groups. Invention VII requires administration of an IL-11R antibody which inhibits interactions between IL-11 and IL-11R, which is not required by any of the other groups. Invention VIII requires administration of an IL-11R antibody which inhibits the interaction between IL-11R and gp130, which is not required by any of the other groups. Invention IX requires administration of transcribable genetic material, which is not required by any of the other groups. Invention XI requires purification procedures, which is not required by any of the other groups. Invention XIII requires use of assays, which is not required by any of the other groups. Therefore, a search and examination of all of the methods in one patent application would result in an undue burden, since the searches for the methods are not co-extensive, the classification is different, and the subject matter is divergent.

Similarly, although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Groups X and XII are directed to products that are distinct both structurally and functionally, are not required one for the other, and are therefore patentably distinct. Further, each Invention requires a unique search which does not overlap with the others.

The remaining pairs of Inventions are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method of each remaining Invention pair does not require the product of the Invention pair.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements and different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

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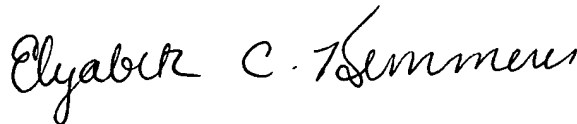
or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D. whose telephone number is (703) 308-2673. The examiner can normally be reached on Mon.-Thurs. and alternate Fri., 6:30-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D. can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

ECK
August 29, 2006

A handwritten signature in cursive script that reads "Elizabeth C. Kemmerer".

ELIZABETH KEMMERER
PRIMARY EXAMINER